Public-Private Partnerships (PPPs):

Fundamentally Limited in their Ability to Deliver Equitable Access to Pharmaceuticals within the TRIPS framework

Caroline Whidden

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INTRODUCTION

The nature of the contemporary global trading system has been largely shaped by international agreements negotiated during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) throughout 1986-1994. The challenges faced by developing countries to implement many of these agreements have far-reaching implications for their sustainable socioeconomic development.[1] One such agreement, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, continues to present a number of obstacles for countries in the developing world, particularly in relation to the procurement of pharmaceuticals to promote and ensure access to high-quality healthcare.

World Trade Organization's (WTO) TRIPS Agreement is the global governance mechanism designed to protect the intellectual property of people or corporations in the international trading system. Under the Agreement, members of the WTO must adopt and enforce domestic legislation that protects the intellectual property rights (IPRs) of multi-national corporations such as pharmaceutical companies. IPRs are defined by the WTO as "rights given to persons over the creations of the minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time."[2] The overriding challenge for developing countries is to "interpret and implement the obligations, rights, and flexibilities under the TRIPS Agreement in ways that are internationally acceptable, yet still protect public health by ensuring access to high-quality, affordable medicines."[3]

Public-private partnerships (PPPs) have emerged as the most innovative attempt to create a system within the framework of TRIPS that will effectively deliver pharmaceuticals to people in societies where the public sector lacks the resources, and where the private sector lacks the market incentive, to adequately respond to the crisis independently. These partnerships involve the collabouration of financial resources from public institutions and corporate expertise and commodities. Despite the fact that PPPs have made significant contributions to combating some 'neglected' diseases, several challenges and limitations exist that have prevented these partnerships from making anything but minor changes, and from contributing effectively to enhancing the equity of global health. Based on these limitations, the idea of attempting to address the problem of global health inequity through PPPs is fundamentally flawed. PPPs cannot displace the ultimate responsibility of national governments and intergovernmental institutions to ensure people's right to high-quality and equitable healthcare. An imaginative re-thinking of the delivery of a public good and basic human right is required in order to adequately address the pressing issue of global health inequity.

In sum, this paper will attempt to outline and provide a context for the role of inadequate and

[1] Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa: Trade-Related Aspects of Intellectual Property Rights Flexibilities* (Washington: The International Bank for Reconstruction and Development/The World Bank, 2008), 1-27.

[2] World Trade Organization, "TRIPS: What are intellectual property rights?" http://www.wto.org/english/tratop_e/trips_e/intel1_e.htm.

[3] Osewe, 2008, 2.

inequitable access to pharmaceuticals in the global health crisis, introduce PPPs as the most innovative model to date for addressing the issue, and discuss its fundamental limitations. To begin, a contextual overview will be provided of how the global pharmaceutical industry is regulated by the TRIPS Agreement, and how this has changed and evolved since the Uruguay Round. The characteristics of pharmaceuticals that make them susceptible to distortions associated with private intellectual property will be described. This paper will then attempt to analyze the question of whether it is the public, private or a collabouration between the two that should be held responsible for enabling and ensuring equitable access to high-quality, affordable medicines. A critical analysis of PPPs will be provided by discussing their successes and limitations within the global framework of intellectual property rights established by the TRIPS Agreement. Finally, the conclusion will emphasize the potential for an imaginative rethinking of the way life-saving medicines are delivered, away from a profit-oriented mentality.

"PPPs CANNOT DISPLACE THE ULTIMATE RESPONSIBILITY OF NATIONAL GOVERNMENTS AND INTERGOVERNMENTAL INSTITUTIONS TO ENSURE PEOPLE'S RIGHT TO HIGH-QUALITY AND EQUITABLE HEALTHCARE. AN IMAGINATIVE RE-THINKING OF THE DELIVERY OF A PUBLIC GOOD AND BASIC HUMAN RIGHT IS REQUIRED IN ORDER TO ADEQUATELY ADDRESS THE PRESSING ISSUE OF GLOBAL HEALTH INEQUITY."

REGULATION OF THE GLOBAL PHARMACEUTICAL INDUSTRY BY THE TRIPS AGREEMENT

The very few firms that operate within the pharmaceutical industry, under near monopolistic conditions, view the patent system as essential to their business model. Under the basic concept of the patent system, an inventor is granted a limited monopoly for a period of time, generally twenty years, during which such exclusivity generates high prices for the product. The consequent profit provides the incentive for investment in the very costly research and development (R&D) process that is necessary to bring a new drug to market. However, most drugs are produced from cheap basic chemicals, rendering the marginal cost of production extremely low.[4] The industry thus seeks intellectual property protection to prevent countries with limited innovative capacities, but with sufficient technical and manufacturing abilities, from imitating production and hindering the profit margin of the original developer by selling valuable drugs at low cost. When a patent expires, the price falls as generic competitors enter the market.[5]

Individual pharmaceutical corporations and the industry's lobby group, Pharmaceuticals Research and Manufacturers of America (PhRMA) – a group of 100 of the biggest drug companies in the world, with seven lobbyists for every congressman in Washington and hundreds more in Europe – led the effort to have IPRs considered by the Uruguay Round of multilateral trade negotiations in the 1980s and 1990s.[6] PhRMA spent millions of dollars lobbying Western governments to strengthen patent protection and to extend it internationally

[4] Amir Attaran and Brigitte Granville, *Delivering Essential Medicines: The Way Forward* (London: Royal Institute of International Affairs, 2004), 10-12.
[5] *Ibid.*
[6] James Orbinski, *An Imperfect Offering: Humanitarian Action in the 21st Century* (Toronto: Doubleday Canada, 2009), 353.

through the TRIPS Agreement, "an agreement that was all but written by PhRMA for implementation through the WTO."[7]
The TRIPS Agreement explicitly protects IPRs in the pharmaceutical sector. Article 27 stipulates that "patents shall be available for any inventions, whether products or processes, in all fields of technology."[8] Up until the negotiations of TRIPS, individual countries possessed the authority to determine which commodities they would provide with IPR protection. Many poorer countries provided no IPR protection to pharmaceuticals since they lacked domestic productive capacity in this sector, and many in fact encouraged imitation of foreign innovation in order to lower the cost of providing public health benefits to their populations.

Since its inauguration with the completion of the Uruguay Round in 1994, the TRIPS Agreement has come under frequent challenge in regards to pharmaceutical trade. The specific context for this challenge involved the HIV/AIDS pandemic in developing countries, particularly when US-based transnational producers threatened sanctions against those they charged in violation of their IPRs, according to their interpretation of the TRIPS. In 1997, both Brazil and South Africa passed domestic legislation in response to the desperate need to combat a public health crisis. The US filed complaints to the WTO that the practice of allowing production in Brazil, and importation in South Africa, of generic medicines effectively discriminated against exports of these drugs from the foreign-based companies that held the patents. Resistance came from governments of developing countries that challenged the interpretation of the Agreement, as well as in the form of widespread protests from non-governmental organizations, activists and civil society.[9]

The 2001 WTO Ministerial Conference in Doha, Qatar acknowledged the widespread resistance and produced the Declaration on TRIPS and Public Health known as the Doha Declaration. The Doha Declaration affirmed the right of governments to take whatever measures necessary to ensure public health, even when those measures conflict with the IPRs of patent holders as outlined in TRIPS.[10] Although many barriers to delivering essential medicines continue to exist, the Doha Declaration is universally acknowledged as a significant achievement as it officially recognized the primacy of public health over private intellectual property.[11] It also clarified the flexibilities regulated mainly under Articles 30 and 31 of the Agreement, particularly that of compulsory licensing, which allows production of a patented product or process for a domestic market without the consent of the patent owner.[12]

Following the optimism that stemmed from the Doha Declaration, the WTO failed to resolve the outstanding issue of the availability of compulsory licensing exceptions to patent protection for those countries experiencing a public health crisis with insufficient manufacturing capabilities. The only option for these countries to address their domestic health crisis was to import generic drugs produced elsewhere. Two years following the Doha Declaration, the 2003 Decision, also referred to as the 'Paragraph 6 Decision', allowed generic copies of patented drugs made under compulsory licenses to be exported to countries

[7] *Ibid.*
[8] World Trade Organization, "TRIPS: PART II – Standards concerning the availability, scope and use of Intellectual Property Rights," http://www.wto.org/english/tratop_e/trips_e/t_agm3_e.htm.

[9] Donald G. Richards, *Intellectual Property Rights and Global Capitalism: The Political Economy of the TRIPS agreement* (New York: M.E. Sharpe Inc., 2004), 143.
[10] Ellen Hoen, "TRIPS, pharmaceutical patents, and access to essential medicines: A long way from Seattle to Doha," *Chicago Journal of International Law* 11.08 (2003): 50.
[11] *Ibid.*
[12] Bryan C. Mercurio. "TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World," *Marquette Intellectual Property Law Review* 8.2 (2004): 230.

that lack production capacity of their own.[13]

However, obtaining compulsory licensing for the production of generic drugs for either domestic markets or for export requires certain conditions and procedures, as cited in Article 31. Among these are the conditions that the patent holder shall receive appropriate financial compensation and that such compensation shall take into account the economic value of the license and be subject to judicial review. Under "circumstances of extreme urgency" or for "national emergencies", the first condition to apply for a license – having already tried and failed to negotiate a voluntary license with the patent holder on reasonable commercial terms – can be bypassed.[14]

Article 30, which grants these flexibilities, is written very generally, and as a consequence has triggered many controversies regarding its interpretation. One section of Article 30 states, "exceptions do not *unreasonably* conflict with a normal exploitation of the patent and do not *unreasonably* prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties"[15] (emphasis added). Just as it was a leading actor in the creation of the agreement, the US pharmaceutical industry has always played a strong role in its interpretation and application. Although present in the text, in practice the flexibilities to ensure that the agreement does not prevent member states from taking any measures to protect public health do not exist.

[13] World Trade Organization, "Compulsory Licensing of Pharmaceuticals and TRIPS," http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.
[14] World Trade Organization, "Compulsory Licensing of Pharmaceuticals and TRIPS."
[15] World Trade Organization, "TRIPS: PART II – Standards concerning the availability, scope and use of Intellectual Property Rights."

ROLES AND LIMITATIONS OF PUBLIC-PRIVATE PARTNERSHIPS IN ADDRESSING INEQUITABLE ACCESS TO PHARMACEUTICALS

Left to its own profit-seeking motives, the private sector cannot be trusted with the responsibility of ensuring that healthcare reaches the people in our world that are disproportionately affected by the burden of disease. These firms will not serve a market that fails to meet minimum rates of return on research, development and marketing, and as a result, there exists a grave imbalance between pharmaceutical innovation and global burdens of disease. In fact, 90 per cent of all annual global spending on health research and development aims at addressing only ten per cent of the world's disease burden.[16]

Access to quality healthcare is a human right, and lifesaving drugs are a form of public good. There is, therefore, a requirement for some level of public provision of pharmaceuticals and healthcare in general. At the national level, the public sector does perform this role to a limited yet important extent in developed countries. In the US the Centers for Disease Control and the National Institute of Health dedicate substantial financial and human resources to R&D to combat a variety of diseases. In many developing countries, however, inadequate financial and human resources, as well as inefficiencies and issues of accountability and transparency in the public sector have impeded efforts by national governments to deliver healthcare. "With inequities in access to healthcare and essential medicines widening both within and between nations, the need for additional resources and efficient delivery strategies has never been more pressing."[17]

On the international stage, the United Nations Human Rights Commission, having for several

[16] Global Health Watch. *Global Health Watch 2005-2006: An Alternative World Health Report* (London: Zed Books Ltd, 2005), 100-119.
[17] Augustine D. Asante and Anthony B. Zwi. "Public-private partnerships and global health equity: prospects and challenges," *Indian Journal of Medical Ethics* IV.4 (2007): 176.

years recognized the HIV/AIDS scourge as a human rights issue, passed a resolution in 2001 that called on states "to facilitate, wherever possible, access in other countries to essential preventative, curative, or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS [...] as well as to extend the necessary cooperation, wherever possible, especially in times of emergency."[18] However, there still exists a real disconnect between the formal recognition of this international public responsibility and the actual execution or action take to ensure it is upheld.

PPPs have been explored as the newest mechanism to mobilize support and resources to combat neglected diseases that disproportionately affect the world's poor. These are cooperative working arrangements involving the expertise of a private body, such as a corporation or an NGO, and the financial resources of a government agency either at the sub-national, national or international level. The Medicines for Malaria Venture and the International AIDS Vaccine Initiative are well-known international public-private partnerships among the 80-90 that currently exist.

Enthusiasm surrounding the promise of PPPs to improving equity in access to essential drugs, while enhancing research into the most neglected diseases, is shared by intergovernmental organizations, pharmaceutical companies and governments in the global north and South.

> The UN and its agencies have been at the forefront of engaging with the private sector in an attempt to foster collabouration that would deliver more resources for health in poorer countries. The WHO has identified partnerships with civil society organizations, philanthropic foundations and the for-profit private sector as key to the future of global health.[19]

The term "partnership" can have a variety of different meanings and has been used to describe various types of collabourations between different actors. The WHO defines PPPs as the "means to bring together a set of actors for the common goal of improving the health of a population through mutually agreed roles and principles."[20] Three main foci for PPPs in the health sector have been identified: products, outcome and activities.[21] Product-oriented partnerships involve efforts to increase investments in R&D for new drugs, vaccines and diagnostic tests for neglected diseases that face a dire lack of funding. These partnerships involve pharmaceutical companies that possess the technological and manufacturing expertise, paired with funding from public institutions and philanthropic foundations. Outcome-oriented partnerships involve government institutions, industry and private donors coordinating to raise awareness and resources to fight poverty-related diseases. Finally, activity-oriented partnerships are collaborations of different organizations that work on the development of a certain drug for a particular disease. When analyzing the effectiveness of PPPs in achieving their fundamental goal of improving delivery of and access to pharmaceuticals, it is important to distinguish between PPPs with varying, yet complementary, specifically targeted objectives.

The purpose of PPPs has been to tackle the public policy failure in the area of drugs for neglected diseases, and in some cases, they have been successful. Physician, humanitarian activist and former president of Médecins Sans Frontières, James Orbinski makes the clear argument that, "while the creation of a new medicine or vaccine for a neglected disease cannot be seen as a bad outcome, it can only be seen as a good

[18] Richards, 2004, 161.

[19] Asante and Zwi, 2001, 176.

[20] Asante and Zwi, 2007, 177.

[21] Robert G. Ridley, "A role for public-private partnerships in controlling neglected diseases," *Bulletin of the World Health Organization* 79.8 (2001): 771.

one if equitable access for all those who need it is achieved."[22] It is the issue of global inequity in relation to access that must be placed at the forefront of the PPP agenda in order to effectively address the global health crisis. The inequity gap in healthcare between rich and poor countries must be bridged by extending access to medicines and vaccines to a broader range of global citizens – including those who cannot pay.

Largely as a result of efficient and targeted public-private partnerships, there have been some significant improvements in access to treatment and care in lower-income countries, particularly in regards to HIV/AIDS and other neglected diseases such as leprosy, malaria, and tuberculosis. However, it is these diseases for which there is both an unmet need in the global south and a potentially lucrative market in the North – for example, the Northern market for new tuberculosis drugs, travelers' antimalarials, and HIV/AIDS vaccines – that get attention from PPPs. They do not target the 'most' neglected diseases, like leishmaniaisis, trypanosomiasis, and Buruli ulcer, for which there exists no consumer purchasing power.[23]

The profit motives of the private sector compromise the viability of PPPs to improve global health equity. In order to secure cooperation from a private corporation, PPPs often face the difficulty of having to generate adequate monetary returns that are comparable to the levels of profit the corporation would expect to realize if it were operating independently.[24] In addition, many powerful pharmaceutical companies involved in PPPs have also independently promoted policies limiting the ability of governments in developing countries to use TRIPS flexibility to improve drug access.

Another major challenge in achieving global health equity is the limited transparency and accountability surrounding PPPs. Often the details of partnership arrangements with the private sector, such as the process of selecting private partners, the setting of targets to be achieved and the formulation of management guidelines are not open to public scrutiny.[25] This lack of transparency makes it difficult to determine who should be held accountable for achieving targets set by the PPP. The public sector theoretically is accountable to the people, whereas the private sector is accountable to shareholders, who are typically more concerned about returns on investment than improving health equity. Compounding the problem is the fact that for a variety of factors including the lack of tax revenue, governments of poor developing countries are less accountable to their domestic population than they are to powerful foreign actors, in this case transnational pharmaceutical companies, with whom they need to maintain good relations.

The PPP model embodies the 'top-down' approach to development, which has proven in recent history to be highly ineffective. "As [PPPs] are usually established at the global level, the extent to which recipient-country governments are involved in their decision-making and priority-setting can be extremely limited."[26] Developing countries that enter into direct arrangements with private companies, often backed by powerful governments, are likely to have a weak negotiating position. In addition, the direct benefits to the lives of the beneficiaries of these PPPs are "likely to be short term, since few have been effectively integrated into national health systems."[27]

In addition to the challenges and limitations mentioned above, global health equity cannot be effectively promoted through partnerships that focus exclusively or narrowly on improving drug access. Equity requires social structures and arrangements that allow people to access health services. If PPPs concentrate "simply

[22] Orbinski qtd in Ridley, 2007, 78.
[23] Orbinski qtd. in Ridley, 2007, 79.
[24] Richards, 2004, 164.
[25] Asante and Zwi, 2007, 178.
[26] Attaran and Granville, 2004, 15.
[27] *Ibid.*, 109.

on the number of tablets distributed rather than on the underlying capacity of health staff to reach villages, then the improvements will be superficial."[28] New medicines and vaccines, together with technology transfer and capacity-building initiatives in developing countries must be complementary goals for PPPs. Pfizer, for example, has said that it "is focusing its efforts on product donations which, in [its] view, provide the most direct, least costly, and fastest means to address access problems in developing countries without extensive public infrastructure."[29] If low cost and speed is the motivation for the private sector in these partnerships, then "like the many vertical programs that have gone before, [PPPs] will not only fail to build the blocks of the health system needed in the long term but may also undermine in the short term what already exists."[30]

CONCLUSION

Pharmaceutical products are indispensable to any health system; they are a major means by which to deliver therapy to fight disease and improve the quality of life of people around the world. Access to vital and high-quality medicines can be seen as a basic human right, and indeed, as a matter of life or death in many situations. It is however, very important to recognize that access to pharmaceuticals is one facet of many in relation to global health. There are many interrelated social, economic, environmental, and other factors – some of the most basic being the lack of infrastructure such as roads and hospitals[31] – that need to be in place in order to achieve quality of health as a person and as a community, and in order to achieve equity of health as a nation and a globe.

PPPs show promise in contributing to the improvement of global health by combining the different skills and resources of the public and private sectors in innovative ways, but cannot be regarded as panaceas in-and-of themselves.[32] PPPs should not be expected to substitute for action on responsibilities ultimately of the public sector. In a round table discussion compiled by Ridley, James Orbinski articulated this claim eloquently:

> Even with a clear vision and mission, public-private partnerships cannot displace the responsibility of government to ensure and promote people's right to equitable access to health care, and to set the heath agenda both nationally and globally [...] Governments still have a duty to ensure that appropriate resources and capacity exist in independent national and intergovernmental institutions to set, drive, monitor and critically evaluate the national and global health agenda. This is a minimum requirement, and goes far beyond the disease-specific initiatives which typify most new public-private partnerships.[33]

It might be easier to make the claim that given the unlikeliness of a radical rethinking, PPPs are at least an attempt to harness the private sector to act outside the scope of its profit-seeking motives. Indeed, they are a step in the right direction, but that is not good enough. National governments and collective bodies of intergovernmental organizations must recognize their responsibility to advocate for the people and to place the public good ahead of profit and power-seeking motives. When it comes to essential and lifesaving drugs, there is absolutely no reason – including money – why some people should have the right to access while others are denied.

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[28] Attaran and Granville, 2004,112.
[29] *Ibid.*
[30] *Ibid.*
[31] Andrew Witty, "New strategies for innovation in global health: a pharmaceutical industry perspective," *Health Affairs* 30.1 (2011): 123.
[32] Roy Widdus, "Public-private partnerships for health: their main targets, their diversity, and their future direction," *Bulletin of the World Health Organization* 79.8 (2001): 718.
[33] Orbinski qtd in Ridley, 2001, 777.